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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

February 20, 1998

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-09-98W

Francesco Pompei, President
Exergen Corporation
51 Water Street
Watertown, MA 02172

Dear Mr. Pompei:

During an inspection of your establishment located in Watertown, Massachusetts on January 26,27,28,30, 1998, our investigator determined that your establishment manufactures electronic infrared thermometers. Electronic infrared thermometers are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

1. Failure to record the quantity rejected in the Materials Inspection Report (MIR) as required by Final Inspection Procedure QAP #10.0001, Rev 5.

2. Failure to maintain records of rework activities on devices that were rejected.

3. Failure to update manufacturing procedures to reflect procedures actually in use on 1/28/98; eg., the use of black body apertures.

4. Failure to document the reasons for not evaluating complaints as required by your complaint handling procedure, QAP #14.002.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. Your are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge response dated 2/9/98 to the FDA-483 by Gerald Clay. It does appear to adequately address the items covered in the FDA-483.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject device has been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to E. Frank Gesing, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180.

Sincerely,

John R. Marzilli
District Director
New England District